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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,263	11/03/2003	Huda Akil	020885-000620US	7036

20350 7590 07/13/2007

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,263	AKIL ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 24 April 2007 have been entered. Claims 2 – 30 are canceled; claims 31 – 33 are new. Claims 1 and 31 – 33 are pending and under examination.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 April 2007 has been entered.

Withdrawn Rejections and Objections

3. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection under 35 USC 112, first paragraph, for lack of enablement commensurate in scope with the claims (paragraph 4 in the office action mailed 24 October 2006) is withdrawn. The claims are now limited to methods of determining the likelihood a subject has (claim 1) or had (claim 32) major depression, whereas previously the claims were drawn to determining predisposition for depression. As the amendments change the scope of the claims to what is reasonably enabled by the specification, the rejection is withdrawn.

B. The rejection under 35 USC 112, first paragraph, for recitation of new matter (paragraph 7 in the office action mailed 24 October 2006) is withdrawn in light of the amendments which remove the new matter. However note the new rejection below, necessitated by applicant's amendment, for recitation of new matter.

Maintained Rejections and Objections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 31 – 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "selectively associates" in claims 1 and 32 is a relative term which renders the claim indefinite. The term "selectively associates" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

This rejection stands for the reasons of record. While applicant has deleted "selectively associates" from claim 1 part (ii), the term remains in parts (iii) and (iv) and is in new claim 32, parts (iii) and (iv). It is recommended that applicant delete the term "selectively" in order to overcome this rejection. As both independent claims 1 and 32 require comparing the detected level of associated probe with a control, the detection of a different amount of probe binding in one sample or the other would reasonably be a difference that is specific to a change in the amount of detected nucleic acid.

Double Patenting

5. Claims 1 and 31 – 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 – 4, and 6 – 10 of copending Application No. 11/158530. Although the conflicting claims are not identical, they are not patentably distinct from each other because they appear to be identical with the exception of the numbers of the table to which claim 1 of '530 refers. The specification of '530 application clearly encompasses detection of FGFR2 nucleic acid (see p. 67 paragraph 294). Thus the claims in the '530 application, read in light of that specification, would render obvious the pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant did not traverse this rejection so it stands for the reason of record.

New Rejections

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 31 – 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Independent claims 1 and 32 are each drawn to methods which require "a nucleic acid probe which it least 95% complementary to mRNA encoding FGFR2". While the specification as filed discloses a single example of FGFR2 nucleic acid (Table 4, which includes nucleic acid encoding human FGFR2), and contemplates use of nucleic acids at least 95% identical to disclosed nucleic acid sequences (paragraph [67] for example), the specification does not provide support for methods of using probes 95% identical to all FGFR2-encoding sequences, as now claimed. The specification discloses that nucleic acids listed in Tables 1 – 8 are associated with mood disorders (see paragraph [84]). Tables 4 and 5 each list the nucleic acid sequence GenBank Accession number M80634 (SEQ ID NO:1), which encodes human FGFR2 protein. The specification as filed reasonably provides support for contacting nucleic acid with a nucleic acid at least 95% identical to SEQ ID NO:1. However the disclosure as originally filed does not provide support for methods of using nucleic acids at least 95% identical to FGFR2-encoding nucleic acids, which can be of different sequences from that of SEQ ID NO:1. Note that human FGFR2 is encoded by multiple nucleic acids of different lengths and sequence. See attached printout Gene ID:2263, human FGFR2. Note particularly p. 13 of the printout, which lists multiple mRNAs encoding human FGFR2. AB030073 is 2941 nucleotides long, AB030074 is 2876 nucleotides long, AB030075 is 3071 nucleotides long. Note this list is not exhaustive but illustrates that applicant has not disclosed the full genus of mRNAs that encode FGFR2 protein, which could be of any species, or even the more limited sub-genus of mRNAs that encode human FGFR2. Rather applicant has disclosed methods of detecting SEQ ID NO:1, which is 3106 nucleotides long and therefore is clearly not identical to any of the three nucleic acids set forth above. Clearly the set of nucleic acids at least 95% identical to the full-length complement of SEQ ID NO:1 is smaller than the set of nucleic acids "at least 95% complementary to mRNA encoding FGFR2" as recited in the claimed methods. While there is support for the former, there is not support use of the latter.

Amendment to recite "at least 95% identical to the full-length complement of SEQ ID NO:1" is recommended to overcome this rejection. In order to expedite prosecution, applicant

may consider amending dependent claims 31 and 33 to recite "... fully complementary to SEQ ID NO:1", which would provide proper antecedent basis for the dependent claims.

7. Claims 1 and 31 – 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Independent claims 1 and 32 are drawn to methods comprising contacting tissue with "a nucleic acid probe which it least 95% complementary to mRNA encoding FGFR2". The specification fails to disclose any sequence encoding FGFR2 with the exception of SEQ ID NO:1. As explained above, there are multiple nucleic acid sequences encoding FGFR2 in humans, which are not described in the specification. The FGFR2 protein and encoding nucleic acids have been identified in several other species as well. The specification does not disclose the sequence of those nucleic acids, and does not contemplate their use in the claimed methods. The skilled artisan cannot visualize which nucleic acid sequences are to be used in claims 1 and 32, as the specification does not disclose any FGFR2-encoding sequence other than SEQ ID NO:1.

Amendment to recite "at least 95% identical to the full-length complement of SEQ ID NO:1" is recommended to overcome this rejection.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner

Daniel E. Kolker, Ph.D.
July 2, 2007